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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/537,416	03/29/00	TAKASHIMA Y	Q58481

HM12/0403

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EXAMINER	
SAUCIER,S	

ART UNIT	PAPER NUMBER
1651	7

DATE MAILED: 04/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/537,416	Takashima et al.
Examiner	**Group Art Unit**
Sandra Saucier	1651

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-9 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-9 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4, 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-9 are pending and are considered on the merits.

Specification

The disclosure is objected to because of the following informalities:
microorganism names are not italicized;
"asymmetric" is misspelled throughout the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

DEPOSIT

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to a specific microorganism. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the specification or record that the microorganism is readily available to the public.

The objection and accompanying rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria, assurance must be provided to the effect that:
(1) during the pendency of the application, access to the cultures will be made available to one determined by the Commissioner to be entitled thereto;
(2) any restrictions on availability of the deposits to the public will be irrevocably removed upon the granting of a patent;
(3) the deposits will be maintained for a term of at least of 30 years from the date of deposit and at least 5 years after the last request for the material;
(4) a viability statement in accordance with the provisions of 37 CFR 1.807; and
(5) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

Assurance may be provided in the form of an affidavit, declaration or averment under oath or by a statement of the attorney of record over her or his signature and registration number.

The specification must also state the date of deposit, the number granted by the depository and the name and address of the depository. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

If the microbes are already in the public domain, I. e. in a catalog which offers them for sale to the public, a statement to that effect will suffice to overcome the rejection.

INDEFINITE

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The name of the microbes should be italicized.

"Asymmetric' is misspelled in claims 1 and 8.

All parenthesis and some of the parenthetical material should be removed because it cannot be determined if the parenthetical material is intended to further limit the claim.

Claim 1 recites that "said ability being not inhibited *seriously*" without giving any parameters as to what amount of inhibition might be considered to be serious. Thus, the metes and bounds of the claim cannot be determined.

Claims 2 and 9 fail to further limit claim 1 and 8 respectively. If applicant can name another optical isomer of an amino acid with the optically active carbon being the α carbon as is required by the limitations, other than D or L forms, the rejection may be overcome.

Claim 3 is confusing. Is it trying to express that the amino acid substrate is a mixture of D, L isomers?

Claim 4 recites "whole" cell. Does this mean that the cell is intact (unbroken) or does it mean that a broken cell is used as long as all of the cell parts are present.

Claims 5-7 recite "derived". Please used "obtained" instead to derived as the term, derived, has multiple meanings, Such as making chemical derivatives of the biological material, which is clearly beyond the scope of the instant disclosure.

Claim 5 has "*Nocardia*" misspelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States, (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, 5, 8 and 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 4,510,246 [A].

The claims are directed to a process of converting an enantiomer of an amino acid of formula 1 to the opposite enantiomer using a biological material

which is not inhibited by the claim specific amino acid transferase inhibitors.

US 4,510,246 discloses the use of epimerase obtained from *Streptomyces clavuligerus*, *cattleya* or *lipmanii* to epimerise isopenicillin N to penicillin N (col. 4, l. 1-10).

Claims 1-4, 8 and 9 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 6,204,050 [B].

US 6204050 disclose the use of 4-hydroxyproline epimerase obtained from *A. baumanni* or *S. marcescens*, which may be used as whole cells, cell extracts or purified enzyme (col. 2, l. 40) to contact at least one of trans-4-hydroxy-D-proline and cis-4-hydroxy-L-proline (col. 2, l. 55).

Claims 1, 2, 5, 8 and 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Laiz *et al.* (IDS).

Laiz *et al.* disclose an epimerase obtained from *Nocardia lactamdurans* or *Streptomyces clavuligerus* and its use to epimerize isopenicillin N.

Claim Rejections - 35 USC § 102/103

Claims 1-3, 5, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by or obvious under 35 U.S.C. 103 over Lim *et al.* [U] in light of the teachings of ATCC Catalog of Bacteria [V].

The claims are directed to a process of converting an enantiomer of an amino acid of formula 1 to the opposite enantiomer using a biological material which is not inhibited by the claim specific amino acid transferase inhibitors.

Lim *et al.* disclose a racemase isolated from *Pseudomonas putida* which acts on the substrates of Table 3 as well as both L and D-threonine.

Since microbes from the genus "*Flavimonas*" have been classified in the past by those of skill in the art as *Pseudomonas*, page 168 ATCC Catalog of Bacteria, use of microbes from genus *Flavimonas* is considered to be the same or obvious over the use of microbes from the genus *Pseudomonas*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gosling *et al.* [W] or Hashimoto *et al.* [X].

The claims are directed to a process of converting an enantiomer of an amino acid of formula 1 to the opposite enantiomer using a biological material which is not inhibited by the claim specific amino acid transferase inhibitors.

The references are relied upon as explained below.

Gosling *et al.* disclose that a microbe from *Rhizobium* possesses an alanine racemase.

Hashimoto *et al.*, deduce that a microbe from *Arthrobacter* has D-alanine racemase activity.

Although the above references do not specifically demonstrate or isolate the racemase activity from the above genera, the named activity strongly suggests that one of skill in the art to use it to catalyze the racemization of alanine from either D or L alanine or a non-racemic mixture of the two isomers.

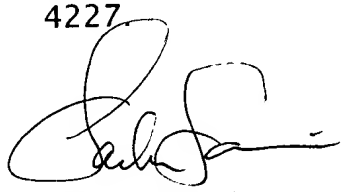
One of skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the resulting compound as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by

the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims directed to the conversion of D-amino acids to L-amino acids or a mixture of D,L-amino acids to L-amino acids of formula (1) using the microbes of the genus/species of claim 6 and the strains of claim 7 appear to be free of the art at this time.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Service Desk at (703) 308-0196. The number of the Fax Center for the faxing of papers is (703) 308-4227.



Sandra Saucier
Primary Examiner
Art Unit 1651
March 27, 2001